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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/527,680	09/15/2005	Lewis George Gradon	(1171/42506) Case 156-PCT	8609
279 7590 03/04/2008 Trexler, Bushnell, Giangiorgi, Blackstone & Marr, Ltd. 105 West Adams Street Suite 3600 Chicago, IL 60603			EXAMINER OSTRUP, CLINTON T	
			ART UNIT 3771	PAPER NUMBER
			MAIL DATE 03/04/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/527,680	Applicant(s) GRADON ET AL.	
	Examiner Clinton Ostrup	Art Unit 3771	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 15 September 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-23 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1-23 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 11 March 2005 is/are: a) ☐ accepted or b) ☒ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☒ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☒ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>3/11/05</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 1-23 are pending in this application. Claims 24-26 have been cancelled.

Priority

The examiner acknowledges this application was filed as a United States National Phase Application of International Application Serial No. PCT/NZ03/00206 filed September 15, 2003, which claims priority to New Zealand Application No. 521744 filed October 2, 2002.

Oath/Declaration

The oath or declaration is defective. A new oath or declaration in compliance with 37 CFR 1.67(a) identifying this application by application number and filing date is required. See MPEP §§ 602.01 and 602.02.

The oath or declaration is defective because: The clause regarding "willful false statements ..." required by 37 CFR 1.68 has been omitted. More specifically, the paragraph reading "I hereby declare that all statements made herein of my own knowledge are true and that all statements made on information and belief are believed to be true; and further that these statements were made with the knowledge that willful false statements and the like so made are punishable by fine or imprisonment, or both, under Section 1001 of Title 18 of the United States Code and that such willful false statements may jeopardize the validity of the application or any patent issued thereon" has been omitted prior to the signature of Lewis George Gradon.

Drawings

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character "1 & 5" have been used to designate headgear. Corrected

drawing sheets in compliance with 37 CFR 1.121(d) are required in reply to the Office action to avoid abandonment of the application.

The drawings are objected to as failing to comply with 37 CFR 1.84(p)(4) because reference character “2” has been used to designate both a hollow body and a mask. See: page 4, lines 20, 21 & 23 of the specification.

The drawings are also objected to as failing to comply with 37 CFR 1.84(p)(5) because they include the following reference character(s) not mentioned in the description: In figure 3, reference characters 21 & 22 are used to designate specific parts in the drawings without designating reference characters 21 & 22 in the specification.

Corrected drawing sheets in compliance with 37 CFR 1.121(d), or amendment to the specification to add the reference character(s) in the description in compliance with 37 CFR 1.121(b) are required in reply to the Office action to avoid abandonment of the application. Any amended replacement drawing sheet should include all of the figures appearing on the immediate prior version of the sheet, even if only one figure is being amended. Each drawing sheet submitted after the filing date of an application must be labeled in the top margin as either “Replacement Sheet” or “New Sheet” pursuant to 37 CFR 1.121(d). If the changes are not accepted by the examiner, the applicant will be notified and informed of any required corrective action in the next Office action. The objection to the drawings will not be held in abeyance.

Specification

The disclosure is objected to because of the following informalities: page 4, line 33 of the specification refers to two US Patent Applications, 09/881,633 (now US Patent No. 6,615,834) and 10/07221. First, 10/07,221 is not a correct US patent application number. For examination purposes, this application number was interpreted as 10/072,271 (now US Patent No. 6,789,541) Secondly, the application should be amended to provide the current status of these applications.

Appropriate correction is required.

Claim Rejections - 35 USC § 101

35 U.S.C. 101 reads as follows:

Whoever invents or discovers any new and useful process, machine, manufacture, or composition of matter, or any new and useful improvement thereof, may obtain a patent therefor, subject to the conditions and requirements of this title.

Claims 1-23 are rejected under 35 U.S.C. 101 because the claimed invention is directed to non-statutory subject matter. Where a claim is directed to an apparatus attached to the human body or any part thereof the claim is directed to nonstatutory subject matter because the claim positively recites part of a human body. See: 1077 Official Gazette, April 21, 1987.

Claims 1, 15 & 16 positively recite parts of a human body as claims 1 and 15 claim a strap "extending around the back of the user's head..." and claim 16 claims "headgear attached to or around the head of said user..." Thus, claims 1, 15 & 16 are directed to non-statutory subject matter and any remaining claims are rejected for depending from a rejected base claim.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-23 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In the claims, when the term "the" or "said" is used, the word or phrase following the term "the" or "said" must have proper antecedent basis. The terms "the" and "said" appear numerous times in the claims without proper antecedent basis for the limitations following the terms "the" and "said."

For example, Claim 1 recites the limitation "the users' face" in line 2; however, there is insufficient antecedent basis for this limitation in the claim. Applicant has provided antecedent basis for "a face of the user" and they are reminded to be consistent in their terminology. Claim 1 also recites the limitation "said mask" in line 4; "the other" in line 5, "said strap" in line 6; "the back" in line 6; and "the user's head" in line 6; all without proper antecedent basis.

Claims 3, 5-6, 9, 12, 15-18, & 20-23 are also rejected for lacking antecedent basis for claim limitations for reasons analogous to those of claim 1.

Claims 1, 15, 16, 17, 18, & 21 are confusing because it is unclear how the claim limitations using the terms comprising or comprises differ from the claim limitation using the terms including or includes. These terms appear to be equivalent and using both

terms causes the claims to be confusing. How do the claim limitations using the terms comprising or comprises differ from those using the terms including or includes?

Claims 1, 12, 15, 17, 18, and 21 are rejected because they provide for the use of an apparatus, but, since the claims do not set forth any steps involved in the method/process, it is unclear what method/process applicant is intending to encompass. A claim is indefinite where it merely recites a use without any active, positive steps delimiting how this use is actually practiced.

Claim 4 is confusing because it is unclear if one end is attached to both the male connector and the female connector; or, is one strap is attached to either a male connector at one end or a female connector at the one end; or if the one strap is attached to a male connector at one end and a female connector at the other end.

The term "substantial movement" in claim 7 is a relative term which renders the claim indefinite. The term "substantial movement" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the invention. It is unclear how "substantial" the movement must be to be included or excluded by the claim.

The term "easily disengage" in claims 12 & 21 is a relative term which renders the claims indefinite. The term "easily disengage" is not defined by the claim, the specification does not provide a standard for ascertaining the requisite degree, and one of ordinary skill in the art would not be reasonably apprised of the scope of the

invention. It is unclear how "easily" the disengagement must be to be included or excluded by the claim.

Any remaining claims are rejected as depending from a rejected base claim.

Claim Rejections - 35 USC § 102

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 1-7 and 14-16 as best understood, are rejected under 35

U.S.C. 102(b) as being anticipated by Starr et al., (5,441,046).

Regarding claim 1, Starr et al., disclose a release mechanism (Figures 10A & 10B) for an interface (26) to enable a user to quickly remove said interface from said users' face, comprising or including: at least one strap (80) having two ends where one end (88) in use is flexibly coupled to releasable connector (10) provided at least on one side of said mask (26), and the other of said two ends (90) flexibly coupled to a mask attachment (44) at the other side of said mask, said strap (80) extending around the back of the user's head, a cord (46) attached to said releasable connector (10) that when said mask is in use and said cord is pulled by said user said releasable connector (10) causes said at least one strap (80 at 88) to be released from said mask thereby causing said mask to fall from said users' face.

Regarding claim 2, Starr et al., disclose a release mechanism with an interface that is a full face mask (26). Regarding claim 3, Starr et al., disclose a release mechanism with a releasable connector harnessing clip (10) comprising a male connector (14) and female connector (88) capable of being coupled together.

Regarding claim 4, Starr et al., disclose a release mechanism with one end of the strap (80 to 84) being attached to one the male connector (14) and a female connector (88). Regarding claim 5, Starr et al., disclose a release mechanism with the male connector flexibly attached to the mask (via 42).

Regarding claim 6, Starr et al., disclose a release mechanism wherein the flexible attachment (42) is achieved by a sliding engagement (pivot) adapted to engage the male connector with said mask (via 46).

Regarding claim 7, Starr et al., disclose a release mechanism according to claim with a sliding engagement adapted to allow said at least one strap (80) substantial movement (the strap can move substantially up and down the user's head) with respect to said mask while still providing a compressive force to seal said mask to the users' face. Regarding claim 14, Starr et al., disclose a release mechanism with a mask attachment that is a releasable connector (10).

Regarding claim 15, Starr et al., disclose a mask having a release mechanism (Figures 10A & 10B) that enables a user to quickly remove said mask (26) from said user's face, comprising or including: at least one strap (80) having two ends (84 & 86) each adapted to, in use, be flexibly coupled to releasable connector (10) at least on one side of said mask and a mask attachment (44) at the other side of said mask, and around the back of the user's head, a cord (46) attached to said releasable connector (10) that when said mask (26) is in use and said cord (46) is pulled by said user said releasable connector (10) causes said at least one strap (80) to be released from said mask thereby causing said mask to fall from said user's face.

Regarding claim 16, Starr et al., disclose a patient interface (26) for delivering a supply of gases to a user comprising or including: headgear (80) attached to or around the head of said user, a sliding engagement (10 & 42) adapted to engage said headgear with said patient interface, release mechanism (10 & 46) coupled between said headgear and said sliding engagement that when actuated by said user causes the separation of said sliding engagement and said headgear.

See: col. 1, line 50 – col. 2, line 49; col. 3, line 10 – col. 5, line 40 & Figures 1-5 & 8-10B.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 8-10, 12, and 17-20, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over Starr et al., (5,441,046), as applied to claims 1, 6, 7, 11 and 16 above and further in view of Van Tassel, (US 6,487,761).

Starr et al., disclose an interface for quickly detaching a mask to a user's face but lacks the connector with a sliding engagement and an elongate member as claimed in claims 8-10, 12, and 17-20.

Van Tassel teaches a quick release connector comprising a sliding engagement that has male and female connectors that slide together to form a connection. Van

Tassel teaches that the connector has elongate members and that the connector is easily released by pulling on a cord. See: col. 1, lines 29-50; col. 2, line 42 – col. 4, line 14 and Figures 2A-6 & 8-9A.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have substituted the cord pulling quick release mechanism of Starr et al., with the cord pulling quick release mechanism as taught by Van Tassel because of the reasonable expectation of obtaining a patient face mask interface with stronger, more secure attachment to the face of a user.

Claims 11-13 & 21-23, as best understood, are rejected under 35 U.S.C. 103(a) as being unpatentable over the combination of Starr et al., (5,441,046), taken together with Van Tassel, (US 6,487,761) as applied to claims 8-10, 12, and 17-20 above and further in view of Gradon et al., (US 2002/0005201), which is available as prior art under 35 U.S.C. 102(b) based on the effective US filing date of the instant application, which is September 15, 2003.

The combined references above disclose a strong, secure, quick release patient face mask interface; however, the combined references lack the loop which passes over and attaches to the mask.

Gradon et al., teach a quick release face mask comprising a loop (120) which extends over the mask and is attached to harnessing clips on each end of the loop. Gradon et al., teach that the loop is engaged with the mask by guides which constrain the loop but allow it to move in and out, meaning the headgear can move laterally, independently of the hollow body. Gradon et al., teach that this type of loop and guide

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engagement allows the mask to maintain its seal over the user's nose and mouth even as the user sleeps and adjusts their sleeping positions. See: page 2, [0035]-[0039] and Figures 4 & 5.

It would have been obvious to one having ordinary skill in the art at the time the invention was made to have modified the quick release patient face mask interface, as disclosed by the combined references above, by using a mask connector with a loop engaged with guides as taught by Gradon et al., because of the reasonable expectation of obtaining a face mask with a strong, secure, quick release mechanism that will stay securely sealed to a patient's face while they are awake, or asleep.

Conclusion

The prior art made of record and not relied upon is considered pertinent to applicant's disclosure: Ogden et al., (5,662,101); Nelson et al., (4,960,121); Eaton et al., (7,066,179); Wiegand (6,550,070); and Amarasinghe et al., (2004/0065328); Ging et al., (2003/0196662) all of which are drawn to face masks.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Clinton Ostrup whose telephone number is (571) 272-5559. The examiner can normally be reached on M-F 7:30-5 pm with alternating Fridays off.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Justine Yu can be reached on (571) 272-4835. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Clinton Ostrup/

Examiner, Art Unit 3771

Clinton Ostrup
Examiner
Art Unit 3771

/Justine R Yu/

Supervisory Patent Examiner, Art Unit 3771